David E. Miller
President

May 21, 2004

Elias A. Zerhouni, M.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Zerhouni:

The Illinois Biotechnology Industry Organization, better known as iBIO™, represents scores of biotechnology companies in this state that work to develop and bring new life-saving and –enhancing drugs and medical products to market.

I am writing out of concern regarding the recent petitions requesting imposition of the march-in provisions of the Bayh-Dole Act against Abbott Laboratories' license for the invention it has productized as the drug Norvir. Such an action would subvert both the language and underlying legislative intent of Bayh-Dole.

The purpose of the Bayh-Dole Act was to stimulate the transfer of technology between university researchers and private sector firms with the resources to develop these inventions and bring them to market so as to benefit the public. The idea was that licensing of federally- funded inventions would provide an incentive for private industry to develop products through the grant of commercialization rights.

Absent these incentives, Congress reasoned, there was little chance of many such potentially useful inventions ever reaching the market. There exists widespread agreement that the incentives provided by the Act have been hugely successful in making new products, including many new drugs, available to the public.

Congress was concerned that in some instances licensed inventions might languish in the hands of the licensees. It therefore built march-in provisions into the law to allow the government to step in if a private company lacked the resources necessary or otherwise failed to bring a product to market or to address public health needs after obtaining its license. The march-in provisions would, in those limited instances, allow the government to grant additional licenses for the same product.

There is nothing in the Act that provides for substitution of a funding agency's judgment on appropriate pricing of the product or allowance for the agency's imposition of price controls through exercise of march-in rights. The only relevant questions under Bayh-Dole are: Is the firm actively making the invention publicly available, and is it benefiting public health needs?

In my research on this matter I have found no claims by any party that Abbott has failed to take, in the Act's language "within a reasonable time, effective steps to achieve practical application of the subject invention" in its "field of use", or that Norvir has failed to effectively address public health needs. Norvir is widely available and has been used effectively by the target HIV patient population. Norvir has strengthened the ability of other drugs, provided by both Abbott and Abbott's competitors in this highly competitive category, to suppress the effects of HIV infection. In some instances, Abbott has made the drug available to people worldwide at no charge and reduced charge.

177 North State Street Suite 500 Chicago, IL 60601 - Tel: (312) 201-4519 - Fax: (312) 553-4355

210233

The petitions for imposition of march-in processes were brought by parties complaining about the price of the product, not its market availability or effectiveness in addressing health needs; what they are saying, in effect, is that Bayh-Dole requires licensees to distribute their products so that every person in every circumstance can access them.

Granting the petitions based on this reasoning would effectively re-write the provisions of Bayh-Dole. Doing so would also subvert the Act's legislative intent.

Widely quoted studies from Tufts University and the Boston Consulting Group indicate that pharmaceutical companies require hundreds of millions of dollars and an average of 10 years to bring a new drug to market. (Abbott reports that it spent more than $300 million dollars to develop Norvir.) More recently, the Bain research group has calculated that, taking into account the many failures for each successful drug candidate, the true cost of each successful drug is over one billion dollars.

Imposing ad-hoc pricing judgments as a pretext for invocation of march-in rights, after a licensee has made substantial investments in testing and product development, would obliterate the very incentives Congress sought to create by enacting Bayh-Dole. The result would be a return to the previous status quo, when taxpayer dollars were invested in research that sat on the shelves.

I therefore urge you to reject these petitions and, in so doing, uphold the language of the Act and its underlying intent to spur development of inventions that benefit the public. Please do not hesitate to contact me if you have any questions regarding this matter.

Sincerely,

David Miller
President

177 North State Street Suite 500 Chicago, IL 60601 - Tel: (312) 201-4519 - Fax: (312) 553-4355